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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/735,402	KURESHY, FAREED	
	Examiner	Art Unit	
	BJ Forman	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 May 2002* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *56-71* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *56-71* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

FINAL ACTION

1. This action is in response to papers filed 22 May 2002 in Paper No. 9 in which amendments to the specification were submitted, claims 1-55 were canceled and new claims 56-71 were added. All of the amendments have been reviewed and entered. The previous rejections in the Office Action of Paper No. 8 dated 22 February 2002 are maintained. New grounds for rejection necessitated by amendments are detailed below. All of the arguments have been thoroughly reviewed but are deemed moot in view of the canceled claims, withdrawn rejections and new grounds for rejection.

Currently claims 56-71 are under prosecution.

Specification

2. The amendment filed 22 May 2002 is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: The following amendments to the claims are deemed new matter: "wherein the multi-functional matrix layer provides reduction of at least one of an autofluorescence of the carrier, an incident-light-absorption of the carrier, and a surface unevenness of the carrier" and "wherein the crosslinking agent comprises a first portion that is coupled to the matrix layer and a second portion that is coupled to the sensing element, and wherein the first and second portions form a non-covalent bond with each other". While the specification broadly teaches the matrix comprises light blocking agents and the surface is optically inactive, are narrower species of the light blocking and optically inactive

described in the specification. Because the specification does not teach or describe the above amendments, the amendments are deemed new matter.

Applicant is required to cancel the new matter in the reply to this Office Action.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 56-71 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

To the extent that the claimed biochip is not described in the instant disclosure, claims 56-71 are also rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention, since a disclosure cannot teach one to make or use something that has not been described.

The recitation "wherein the multi-functional matrix layer provides reduction of at least one of an autofluorescence of the carrier, an incident-light-absorption of the carrier, and a surface unevenness of the carrier" is added to the new independent Claim 1 and new dependent Claim 62. However, the specification fails to define or provide any disclosure to support such claim recitation. The specification teaches "light blocking agents" which renders

the "surface optically inactive thereby mitigating, preventing, minimizing, reducing background fluorescence emanating from the carrier" (page 21, line 20-page 22, line 1). And the specification teaches "optically inactive" is a surface which produces low reflectivity, low fluorescence and low scatter properties" (page 18, lines 16-15). While the specification teaches a surface comprising "light blocking agents" and an "optically inactive" surface, the specification does not teach a multi-functional matrix layer provides reduction of at least one of an autofluorescence of the carrier, an incident-light-absorption of the carrier, and a surface unevenness of the carrier as claimed.

The recitation "wherein the crosslinking agent comprises a first portion that is coupled to the matrix layer and a second portion that is coupled to the sensing element, and wherein the first and second portions form a non-covalent bond with each other" is added to new dependent Claim 66. However, the specification fails to define or provide any disclosure to support such claim recitation. While the specification teaches the crosslinking agents (page 23, line 15-page 25, line 6). The specification does not teach the first and second portions of the crosslinking agent forms a non-covalent bond with each other as claimed.

MPEP 2163.06 notes "IF NEW MATTER IS ADDED TO THE CLAIMS, THE EXAMINER SHOULD REJECT THE CLAIMS UNDER 35 U.S.C. 112, FIRST PARAGRAPH - WRITTEN DESCRIPTION REQUIREMENT. *IN RE RASMUSSEN*, 650 F.2D 1212, 211 USPQ 323 (CCPA 1981)." MPEP 2163.02 teaches that "Whenever the issue arises, the fundamental factual inquiry is whether a claim defines an invention that is clearly conveyed to those skilled in the art at the time the application was filed...If a claim is amended to include subject matter, limitations, or terminology not present in the application as filed, involving a departure from, addition to, or deletion from the disclosure of the application as filed, the examiner should conclude that the claimed subject matter is not described in that application." MPEP 2163.06 further notes "WHEN AN AMENDMENT IS FILED IN REPLY TO AN OBJECTION OR REJECTION BASED ON 35 U.S.C. 112, FIRST PARAGRAPH, A STUDY OF THE ENTIRE APPLICATION IS OFTEN NECESSARY TO DETERMINE WHETHER OR NOT "NEW MATTER" IS INVOLVED. ***APPLICANT SHOULD THEREFORE SPECIFICALLY POINT OUT THE SUPPORT FOR ANY AMENDMENTS MADE TO THE DISCLOSURE***" (emphasis added).

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in-
> (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application published under section 122(b) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or
> (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a).

6. Claims 56-71 are drawn to a biochip comprising a carrier coupled to a multi-functional matrix that is coupled to a sensing element wherein the multi-functional matrix provides reduction of at least one of an autofluorescence of the carrier, an incident-light-absorption of the carrier, and a surface unevenness of the carrier; and wherein the sensing element binds to an analyte that is disposed in a sample fluid when the sample fluid contacts the biochip. As stated above, the limitation, "wherein the multi-functional matrix provides reduction of at least one of an autofluorescence of the carrier, an incident-light-absorption of the carrier, and a surface unevenness of the carrier" is considered new matter because the specification does not provide support for the new limitation. Because the new limitation is considered new matter, the new claims are addressed THREE ways. First, the previous limitations (i.e. "wherein the matrix further comprises light blocking agents" (Claim 42) "wherein the light blocking agents are selected from the group consisting of iron oxide, titanium dioxide and carbon black" (Claim 43)) are substituted for the new limitations. Second, the claims are addressed without the

new matter limitations. Finally, the claims are addressed as amended including the new matter.

7. In the first analysis of the claims, (substituting the previous limitations of Claims 38-55 and especially 38, 42 and 43), the previous rejections are maintained. The previous rejections are detailed in the Office Action of Paper No. 8. The arguments regarding the previous rejections are discussed below.

Response to Arguments

8. Applicant argues that Ershov et al do not teach the newly claimed "matrix that provides reduction of at least one of an autofluorescence of the carrier, an incident-light-absorption of the carrier, and a surface unevenness of the carrier" and therefore do not anticipate the claims. The argument has been considered but is not found persuasive for two reasons. First, the arguments address the newly added limitation (i.e. matrix that provides reduction of at least one of an autofluorescence of the carrier, an incident-light-absorption of the carrier, and a surface unevenness of the carrier) which are considered new matter. Because the arguments do not address the previous rejections and because the arguments address new matter limitations, the argument are not relevant to the previous rejection. Second, the claims are drawn to a biochip comprising a carrier coupled to a matrix that is coupled to a sensing element. Because Ershov et al disclose the structural components of the biochip, they disclose the biochip. The courts have stated that claims drawn to an apparatus must be distinguished from the prior art in terms of structure **rather than function** see *In re Danly*, 263 F.2d 844, 847, 120 USPQ 528, 531 (CCPA1959). "[A]pparatus claims cover what a device is, not what a device does." Hewlett-Packard Co. v. Bausch & Lomb Inc., 909 F.2d 1464, 1469, 15 USPQ2d 1525,1528 (Fed. Cir. 1990) (see MPEP, 2114).

Applicant argues that Havens et al teach away from the instant invention because contrary to the instant invention the detection of Havens' analyte is an electronic detection and

as such the matrix that provides reduction of at least one of an autofluorescence of the carrier, an incident-light-absorption of the carrier, and a surface unevenness of the carrier would be superfluous. The argument has been considered but is not found persuasive for numerous reasons. First, the newly added limitation (i.e. matrix that provides reduction of at least one of an autofluorescence of the carrier, an incident-light-absorption of the carrier, and a surface unevenness of the carrier) is considered new matter and therefore, arguments addressing these limitations are irrelevant. Second, the claims are drawn to a biochip comprising a carrier coupled to a matrix that is coupled to a sensing element. Because Havens et al disclose the structural components of the biochip, they disclose the biochip. The courts have stated that claims drawn to an apparatus must be distinguished from the prior art in terms of structure **rather than function** see *In re Danly*, 263 F.2d 844, 847, 120 USPQ 528, 531 (CCPA1959). "[A]pparatus claims cover what a device is, not what a device does." Hewlett-Packard Co. v. Bausch & Lomb Inc., 909 F.2d 1464, 1469, 15 USPQ2d 1525,1528 (Fed. Cir. 1990) (see MPEP, 2114). Finally, the argument is not found persuasive because contrary to Applicant's assertion, the analyte detection of Havens et al is not electronic. While the biochip of Havens et al utilizes electrophoretic transport (Column 4, lines 40-60) the detection is fluorescent (Column 9, lines 32-65 and Fig. 9 and 10).

Applicant argues that Havens et al, Ershov et al and Chetverin et al do not teach or suggest the newly added limitations i.e. matrix that provides reduction of at least one of an autofluorescence of the carrier, an incident-light-absorption of the carrier, and a surface unevenness of the carrier. The argument has been considered but is not found persuasive for two reasons. First, the newly added limitation (i.e. matrix that provides reduction of at least one of an autofluorescence of the carrier, an incident-light-absorption of the carrier, and a surface unevenness of the carrier) is considered new matter and therefore, arguments addressing these limitations are irrelevant to the previous rejection. Second, the claims are drawn to a biochip comprising a carrier coupled to a matrix that is coupled to a sensing

element. Havens et al and Ershov et al each disclose the structural components of the biochip and hence, they disclose the claimed biochip.

Applicant further argues that there is no motivation to combine the teaching of Havens et al, Ershov et al and Chetverin et al because contrary to the instant invention, the detection of Chetverin et al is an in-situ PCR and therefore teaches away from the claimed invention. In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988)and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, the methods of Havens et al, Ershov et al and Chetverin et al are all drawn to light detection of an analyte. see Havens et al (Column 9, lines 32-65 and Fig. 9 and 10); Ershov et al (Abstract) and Chetverin et al (Column 13, lines 24-55). Therefore, one skilled in the art would have been motivated to combine the light-detection teachings of Havens et al, Ershov et al and Chetverin et al. to thereby optimize analyte detection for the expected benefit of maximizing detection. It is noted that *In re Aller*, 220 F.2d 454,456, 105 USPQ 233,235 states where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum by routine experimentation.

9. In the second analysis of the claims, the claims are addressed without the new matter limitations.

Claim 56, 57 and 59-71 are rejected under 35 U.S.C. 102(e) as being anticipated by Havens et al (U.S. Patent No. 6,306,348 B1, filed 15 July 1999).

Regarding Claim 56, Havens et al disclose a biochip comprising: a carrier coupled to a matrix that is coupled to sensing elements (Column 7, line 20-Column 8, line 45 and Column 9, lines 32-55) wherein the sensing element binds to an analyte that is disposed in a sample fluid when the fluid contacts the biochip (Column 9, lines 52-64).

Regarding Claim 57, Havens et al disclose the carrier comprises an organic or inorganic polymer i.e. silicon, plastic, ceramic and semiconductor materials (Column 4, lines 61-67).

Regarding Claim 59, Havens et al disclose the biochip comprising a hydrophilic layer (i.e. sol-gel composition permeation layer) is interposed between the carrier and multi-functional layer (attachment layer) (Column 8, line 13-Column 9, line 51 and Fig. 9).

Regarding Claim 60, Havens et al disclose the biochip wherein the matrix layer comprises an aqueous solvent i.e. agarose (Column 9, lines 32-36).

Regarding Claim 61, Havens et al disclose the biochip wherein the matrix layer comprises agarose (Column 9, lines 32-36).

Regarding Claim 62, Havens et al disclose the biochip comprise a second matrix layer i.e. a first permeation layer and a second attachment layer (Column 8, line 13-Column 9, line 51 and Fig. 9).

Regarding Claim 63, Havens et al disclose the biochip wherein the sensing element comprises a polypeptide or polynucleotide (Column 6, lines 4-24).

Regarding Claim 64, Havens et al disclose the biochip wherein the sensing element is at least partially embedded within the multi-functional matrix layer (Column 9, lines 32-43 and Fig. 6 and 7).

Regarding Claim 65, Havens et al disclose the biochip wherein the sensing element is coupled to the multi-functional matrix via a crosslinking agent (Column 9, lines 32-43).

Regarding Claim 66, Havens et al disclose the biochip wherein the crosslinking agent comprises a first portion coupled to the matrix and a second portion that is coupled to the sensing element (Column 9, lines 32-43).

Regarding Claim 67, Havens et al disclose the biochip wherein the firs portion comprises streptavidin and the second portion comprises biotin (Column 9, lines 32-43).

Regarding Claim 68, Haven et al disclose the biochip wherein the analyte is selected from the group consisting of an oligonucleotide, a polynucleotide (Column 6, lines 4-24 and Column 9, lines 32-64).

Regarding Claim 69, Havens et al disclose the biochip wherein the sample fluid comprises a subcellular component i.e. oligonucleotide, a polynucleotide and antibody-binding entity (Column 6, lines 4-24 and Column 9, lines 32-64).

Regarding Claim 70, Havens et al disclose the biochip wherein the matrix comprises at least one of a surfactant, a humectant , a buffer and a light blocking agent (Column 8, lines 46-52 and Column 10, lines 10-39).

Regarding Claim 71, Havens et al disclose the biochip further comprising a second matrix layer wherein at least one of the layers comprises a surfactant, a humectant , a buffer and a light blocking agent (Column 8, lines 46-52 and Column 10, lines 10-39 and Fig. 6 and 7).

10. In the third analysis of the claims, the claims are addressed as amended including the new matter limitations.

Claim 56-58 and 60-71 are rejected under 35 U.S.C. 102(b) as being anticipated by Bogart et al (U.S. Patent No. 5,541,057, issued 30 July 1996).

Regarding Claim 56, Bogart et al disclose a biochip comprising: a carrier coupled to a multi-functional matrix that is coupled to sensing elements wherein the matrix provides reduction of autofluorescence of the carrier and incident light absorption via optical thin film anti-reflective layer over the substrate (Column 9, lines 34-51, Column 10, lines 24-34,

Column 45, lines 30-59 and Fig. 7) wherein the sensing element binds to an analyte that is disposed in a sample fluid when the fluid contacts the biochip (Column 9, lines 11-26).

Regarding Claim 57, Bogart et al disclose the carrier comprises an organic or inorganic polymer i.e. silicon, plastic, ceramic and semiconductor materials (Column 15, lines 10-17).

Regarding Claim 58, Bogart et al disclose the carrier comprises an organic polymer selected from the group consisting of polyethylene, a polyester, and a polystyrene (Column 34, lines 47-54).

Regarding Claim 60, Bogart et al disclose the biochip wherein the matrix layer comprises an aqueous solvent i.e. aqueous buffer and gelatin (Column 29, lines 8-24 and Example 19, Column 72, line 50-Column 73, line 18).

Regarding Claim 61, Bogart et al disclose the biochip wherein the matrix layer comprises gelatin (Example 19, Column 72, line 50-Column 73, line 18).

Regarding Claim 62, Bogart et al disclose the biochip comprises a second matrix layer i.e. a receptive material layer and an attachment layer (Column 10, lines 24-34 and Fig. 7) and wherein the second layer is the attachment layer which comprises incident light absorption via optical thin film anti-reflective layer over the substrate (Column 9, lines 34-51, Column 10, lines 24-34, Column 45, lines 30-59 and Fig. 7). The claim is drawn to a biochip comprises a second layer. The claims do not limit the second layer to being disposed between the first layer and the carrier. Therefore, given the broadest reasonable interpretation of the claim, the attachment layer comprising an optical film , anti-reflective film encompasses the claimed second layer. The courts have stated that claims must be given their broadest reasonable interpretation consistent with the specification *In re Morris*, 127 F.3d 1048, 1054-55, 44 USPQ2d 1023, 1027-28 (Fed. Cir. 1997); *In re Prater*, 415 F.2d 1393, 1404-05, 162 USPQ 541, 550-551 (CCPA 1969); and *In re Zletz*, 893 F.2d 319, 321-22, 13 USPQ2d 1320, 1322 (Fed. Cir. 1989) (see MPEP 2111).

Regarding Claim 63, Bogart et al disclose the biochip wherein the sensing element comprises a polypeptide or polynucleotide (Column 27, lines 44-Column 28, line 11).

Regarding Claim 64, Bogart et al disclose the biochip wherein the sensing element is at least partially embedded within the multi-functional matrix layer (Column 28, lines 62-66 and Example 19, Column 72, line 50-Column 73, line 18).

Regarding Claim 65, Bogart et al disclose the biochip wherein the sensing element is coupled to the multi-functional matrix via a crosslinking agent i.e. the attachment layer comprises avidin for avidin-biotin binding (Column 27, lines 22-29).

Regarding Claim 66, Bogart et al disclose the biochip wherein the crosslinking agent comprises a first portion coupled to the matrix and a second portion that is coupled to the sensing element i.e. the attachment layer comprises avidin for avidin-biotin binding (Column 27, lines 22-29).

Regarding Claim 67, Bogart et al disclose the biochip wherein the first portion comprises streptavidin and the second portion comprises biotin i.e. the attachment layer comprises avidin for avidin-biotin binding (Column 27, lines 22-29).

Regarding Claim 68, Bogart et al disclose the biochip wherein the analyte is selected from the group consisting of a receptor, an enzyme, an oligonucleotide, a polynucleotide, a toxin, an antibody, an oligosaccharide and vial epitope (Column 28, lines 11-28).

Regarding Claim 69, Bogart et al disclose the biochip wherein the sample fluid comprises a cell, a subcellular component, a component from a virus or a component from a microorganism (Column 28, lines 6-11).

Regarding Claim 70, Bogart et al disclose the biochip wherein the matrix comprises at least one of a surfactant, a humectant, a buffer and a light blocking agent (Column 8, lines 46-52 and Column 10, lines 10-39).

Regarding Claim 71, Bogart et al disclose the biochip further comprising a second matrix layer wherein at least one of the layers comprises a surfactant, a humectant , a buffer

and a light blocking agent i.e. the receptive material layer comprises a buffer and surfactant (Column 29, lines 8-15).

Claim Rejections - 35 USC § 103

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

12. Claim 59 is rejected under 35 U.S.C. 103(a) as being unpatentable over Bogart et al (U.S. Patent No. 5,541,057, issued 30 July 1996) in view of Havens et al (U.S. Patent No. 6,306,348 B1, filed 15 July 1999).

Regarding Claim 59, Bogart et al teach a biochip comprising: a carrier coupled to a multi-functional matrix that is coupled to sensing elements wherein the matrix provides reduction of autofluorescence of the carrier and incident light absorption via optical thin film anti-reflective layer over the substrate (Column 9, lines 34-51, Column 10, lines 24-34, Column 45, lines 30-59 and Fig. 7) wherein the sensing element binds to an analyte that is disposed in a sample fluid when the fluid contacts the biochip (Column 9, lines 11-26) but the do not teach the biochip comprises a hydrophilic layer between the carrier and the multi-functional layer. However, Havens et al teach a similar biochip comprising a hydrophilic layer (i.e. sol-gel composition permeation layer) interposed between the carrier and multi-functional layer (attachment layer) (Column 8, line 13-Column 9, line 51 and Fig. 9) wherein the sol-gel is adjustable to have a desired pore morphology based on analyte and wherein the sol-gel

maintains its physical properties in various aqueous, chemical and electrical environments (Column 3, lines 16-27). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the sol-gel layer of Havens et al to the matrix of Bogart and to interpose a sol-gel layer between the carrier and matrix based on sol-gel's properties for the expected benefits of obtaining an adjustable and stable matrix as taught by Havens et al (Column 3, lines 16-27).

13. Claim 58 is rejected under 35 U.S.C. 103(a) as being unpatentable over Havens et al (U.S. Patent No. 6,306,348 B1, filed 15 July 1999) in view of Bogart et al (U.S. Patent No. 5,541,057, issued 30 July 1996).

Regarding Claim 58, Havens et al teach a biochip comprising: a carrier coupled to a matrix that is coupled to sensing elements (Column 7, line 20-Column 8, line 45 and Column 9, lines 32-55) wherein the sensing element binds to an analyte that is disposed in a sample fluid when the fluid contacts the biochip (Column 9, lines 52-64) but they do not teach the carrier comprise an organic polymer consisting of polyethylene, polyester or polystyrene. However, Bogart et al teach a similar biochip wherein the carrier comprises an organic polymer selected from the group consisting of polyethylene, a polyester, and a polystyrene wherein the polymer provides a protective shell around a disposable biochip (Column 34, lines 47-54). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the carrier consisting of polyethylene, polyester or polystyrene as taught by Bogart et al to the carrier of Havens et al to thereby provide a protective shell for the obvious benefit of protecting the carrier as taught by Bogart et al (Column 34, lines 47-54).

Prior Art

14. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure:

a. Hahn et al (U.S. Patent No. 6,174,683, B1) teach a biochip comprising a carried, aqueous matrix and sensing elements (Column 4, lines 17-49).

b. Sosnowski et al (U.S. Patent No. 6,051,380, filed 5 December 1997) teach a biochip comprising a carried, aqueous matrix and sensing elements (Abstract and Fig. 19).

15. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

REQUIREMENT TO COMPLY WITH NUCLEIC ACID SEQUENCE RULES

16. The communication filed 22 May 2002 **is not fully responsive** to the Office communication mailed 22 February 2002 for the reason(s) set forth on the attached Notice To Comply With The Sequence Rules or CRF Diskette Problem Report. Applicant must comply with the requirements of the sequence rules (37 CFR 1.821 - 1.825) before the application can be examined under 35 U.S.C. §§ 131 and 132.

Applicant is given A PERIOD OF TIME WHICH IS CO-EXTENSIVE WITH THE TIME TO REPLY TO THE ATTACHED OFFICE ACTION within which to comply with the sequence rules, 37 CFR 1.821 - 1.825. Failure to comply with these requirements will result in **ABANDONMENT** of the application under 37 CFR 1.821(g). Extensions of time may be obtained by filing a petition accompanied by the extension fee under the provisions of 37 CFR 1.136(a). Direct the reply to the undersigned. Applicant is requested to return a copy of the attached Notice to Comply with the reply.

Conclusion

17. No claim is allowed.

18. The examiner's Art Unit has changed from 1655 to 1634. Please address future correspondence to Art Unit 1634.

19. Any inquiry concerning this communication or earlier communications from the examiner should be directed to BJ Forman whose telephone number is (703) 306-5878. The examiner can normally be reached on 6:30 TO 4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones can be reached on (703) 308-1152. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-8724 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

BJ Forman, Ph.D.
Patent Examiner
Art Unit: 1634
July 30, 2002

W. Gary Jones
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